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09/330,384	06/11/1999	RICHARD E. GLIKLICH	OSC99-01	9339

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EXAMINER
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ART UNIT	PAPER NUMBER
2175	

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Please find below and/or attached an Office communication concerning this application or proceeding.

PTO-90C (Rev. 07-01)

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Office Action Summary	Application No.	Applicant(s)	
	09/330,384	GLIKLICH, RICHARD E.	
	Examiner	Art Unit	
	Sam Rimell	2175	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____ .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *10-18 and 20-34* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *10-18 and 20-34* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Sam Rimell
Primary Examiner
AU 2175

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) *4,5* .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

Preliminary Note: The Information Disclosure Statement of June 11, 1999 includes the citation of a reference entitled "1998 Medical Outcomes & Guidelines Sourcebook". The copy of the reference provided only includes a copy of the front page of the book, and a copy of the copyright notices. Since the information provided is apparently incomplete, the reference citation has been deleted from the PTO form 1449 associated with this Information Disclosure Statement. The remaining information provided is complete.

Response to Applicant's Traverse of the Restriction Requirement: Applicant's arguments in traverse of the restriction requirement have been considered but are not well taken. Applicant argues that the classification of group II is in correct, and that class 700, subclasses 91-92 pertain exclusively to gaming devices. This argument is not correct. Subclasses 91-92 of class 700, are relatively generic subclasses that deal with data processing applications that perform statistical analysis and scoring. It is not exclusively dedicated to gaming, and a review of the patents contained in these subclasses reveal many patents that are entirely unrelated to gaming. Applicant also argues that the claims of group II do not indicate the possible application of this invention to word processing, scientific calculation, video games, spread sheets and preparation of web site content. This argument is also not correct. The invention defined by the claims of group II define a computer processor which contains certain specified algorithms. However, the claimed invention is not limited to a processor containing only those algorithms, as evidenced by the use of the term "comprising" in the preamble of each claim. While the claimed processor must at least include the claimed algorithm, there is no indication that the claimed processor must only include the one claimed algorithm. If the processor is a conventional computer system, then it can and will include programs capable of performing word processing, spread sheets, etc.

The restriction requirement is therefore sustained and made final.

Claims 11, 20 and 34 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 11: The phrase "allows the clinical outcome data to be used" makes it unclear as to whether the data is actually being used or not being used.

Claim 20: The phrase "the computing device" lacks antecedent basis.

Claim 34: The phrases "the output is governed" and "governed, in part" are indefinite.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) do not apply to the examination of this application as the application being examined was not (1) filed on or after November 29, 2000, or (2) voluntarily published under 35 U.S.C. 122(b). Therefore, this application is examined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

Claims 10-13, 15-18, 20-24, and 28-31, 33 and 34 are rejected under 35 U.S.C. 102(e) as being anticipated by Brown ('992).

Claim 10: A medical study is selected by selecting a particular patient grouping (see upper left hand corner of FIG. 3). As seen in FIG. 3, this is a grouping of patients having

diabetes. Medical data is entered by the patients using remote input systems (36 and 46 in FIG. 1). The input information from one patient is processed along with data from other patients using a processing algorithm so as to immediately produce the chart of FIG. 3. The chart of FIG. 3 is the clinical outcome of the medical study and is immediately output to the user as a screen display. The data is displayed immediately upon completion of processing.

Claim 11: Since the data is immediately output on the display, it can be used to immediately influence treatment. In particular, the physician can send a correspondence to the patient (FIG.5) to take specific actions in response to the entry of the data.

Claim 12: The correspondence of FIG. 5 indicates that the processing system is aware of the clinician who is using the system, since it automatically creates correspondence which includes the clinicians name. It is therefore clear that the processing system identifies an individual clinician during usage. As seen in FIG. 3, the clinician is presented with one of a plurality of patient groups, selected by the button in the top left corner of FIG. 3. Each patient group represents a medical study. The clinician can select which study to view. The diabetes study is illustrated. The clinician is also presented a list of patients (70).

Claim 13: The study illustrated in FIG.3 will indicate the effects of a diabetes drug on each patient, and compare the effectiveness of this drug for each patient.

Claim 15: The processing algorithm determines if the entered medical data conforms or does not conform to certain standards. The conformance or non-conformance is indicated by specific symbols, which are illustrated in the chart key of FIG. 3. If the data provided by the patient is substantially non-conforming, a trigger event will occur where the non-conforming patient will be indicated by a flashing icon on the display of FIG. 3 (col 7. lines 18-20).

Claim 16: The trigger event is the flashing icon. The trigger event indicates to the clinician that a non-standard data set has been received.

Claim 17: The patient is notified of the non-standard data set by the use of an e-mail correspondence (FIGS 4-5).

Claim 18: The trigger event is triggered by failing to meet anticipated timing for data entry. The timing is a certain period of elapsed days during which non-standard data or no data has been received.

Claim 20: The processing system of Brown ('992) receives sets of medical information from a plurality of patients. The data is maintained in a database (204 in FIG. 6). A first characteristic, such as the group of patients having diabetes can be selected and data processed according to that characteristic. The clinical outcome is the display chart shown in FIG. 3 and is immediately output to the clinician.

Claim 21: The data received from each patient represents an individual set of data. The individual sets of data are compared on the chart of FIG. 3. The data for each set is ranked according to the chart key (68) in FIG. 3. Depending upon the ranking, a different symbol is produced for that set of data.

Claim 22: The chart of FIG. 3 indicates and highlights data which does not conform to certain standards. Patients who do not provide the required data are considered to be at risk. Thus the tool of FIG. 3 also provides a risk assessment.

Claim 23: Non-compliant data leads to a trigger event in which the icon representing the patient begins to flash. The trigger is provided to the clinician. The trigger event also leads to a notification of the patient via e-mail.

Claim 24: The feedback provided to the clinician leads to an immediate notification sent to the patient.

Claim 28: See remarks for claim 20.

Claim 29: Each set of medical data derives from a patient. The clinical algorithm is applied to data supplied by a patient.

Claim 30: The first set of characteristics is the set of patients who have diabetes. The second characteristic is their compliance in providing data. The two characteristics are correlated in the chart of FIG. 3.

Claim 31: The first characteristic can also be a doctor, since the data shown in the display chart of FIG. 3 is unique to one doctor.

Claim 33: The system of Brown is not limited to producing a chart for only one clinician. Individual charts for individual clinicians can be produced and compared, with each chart indicating their relative success at maintaining patient compliance with a specific regime.

Claim 34: The overview chart will be different for each clinician.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claim 32 is rejected under 35 U.S.C. 103(a) as being unpatentable over Brown ('992).

Brown differs from the claims in that it lumps all diabetes patients into a single group, regardless of which medication they are taking. Examiner takes Official Notice that it is well known in the art to study the effects of different medications on different patients as part of FDA

mandated clinical trials. It would have been obvious to one of ordinary skill in the art to modify the system of Brown to provide the overview chart of FIG. 3 organized according to specific drugs provided to patients, rather than only populating the chart with data for patients in a common disease category. This would provide more information to the clinician improve the quality of diagnosis and treatment.

Claims 14 and 25 –27 are rejected under 35 U.S.C. 103(a) as being unpatentable over Brown ('992) in view of Brown ('586).

Brown ('992) differs from claims 14 and 25-27 in that it does not state how the data is obtained. Brown ('586) states that the data for Brown ('992) are partly obtained through a series of questions. As seen in FIG. 5B, the presentation of a first question (124) will influence the questions that follow. For example, if the patient indicates that the device type is a weight scale, the questions will ask what weight was recorded, rather than glucose measurements.

It would have been obvious to one of ordinary skill in the art to modify Brown ('992) to include the data collecting questions of Brown ('586) so as to permit a grater variety of data to be collected. It is also noted that the systems of Brown ('992) and Brown ('586) were developed by the same inventor and are apparently designed to be used to together in a single system.

Any inquiry concerning this communication should be directed to Sam Rimell at telephone number (703) 306-5626.

Sam Rimell
Primary Examiner
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